UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte RICHARD WEISBART and LEON E. BARSTOW

Appeal No. 2006-2745
Application No. 09/966,119

HEARD: October 17, 2006

Before ADAMS, GREEN and LEBOVITZ, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 8 and 28. The only other pending claims (claims 1-7 and 10-27), were withdrawn from consideration as drawn to a non-elected invention. Brief, page 2.

Claims 8 and 28 are reproduced below:

8. A pharmaceutical composition comprising irradiated Cohn Fraction II + III and a pharmaceutically acceptable carrier suitable for oral administration.

28. A composition comprising irradiated Cohn Fraction II + III suitable for oral administration.

The references relied upon by the examiner are:

Kent	6,171,549	Jan. 9, 2001
Hardie	EP 0 064 210 B2	Nov. 11, 1982

GROUNDS OF REJECTION

Claims 8 and 28 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Hardie and Kent.

Claims 8 and 28 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 and 9 of copending U.S. Patent Application No. 09/672,911, in view of Hardie.

We affirm.

DISCUSSION

Obviousness:

Claims 8 and 28 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Hardie and Kent. Appellants do not separately argue or group the claims on appeal. Accordingly, claims 8 and 28 will stand or fall together. Since the claims stand or fall together, we limit our discussion to representative independent claim 28. Claim 8 will stand or fall together with claim 28. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

Claim 28 is drawn to a composition that comprises "irradiated Cohn Fraction II + III." According to claim 28, this composition is "suitable for oral

administration." There is, however, no requirement in claim 28 that this composition be "administered" e.g., to a patient, or that it be administered "orally," as opposed to e.g., intravenously.

According to appellants' specification (page 9), "[a] preferred immunoglobulin composition, Cohn Fraction II + III, contains at least about 30% to about 85% IgG polyclonal antibodies, about 5% to about 30% IgA and about 1% to about 25% IgM and trace amounts of other components. . . ." As the examiner points out (Answer, page 6), Hardie teaches (page 4) an oral composition that contains

> about 1-80% IG [sic], more preferably about 5-50% of which not less than 70% is gamma globulin (IgG). . . . The product may contain other globulins such as IgA, IgM, IgD, and IgE. For example, Cohn Fraction II and III contains the following proportions of the above: about 8 parts IgG to 1 part each of IgA and IgM and traces of IgD and IgE.

In our opinion, but for the requirement in appellants' claim that the composition be irradiated, the oral Cohn Fraction II + III composition taught by Hardie is the same as the Cohn Fraction II + III set forth in appellants' claimed invention.

While appellants acknowledge that Hardie teaches an "orally administerable composition" (Brief, page 6, emphasis removed), they argue that the Cohn Fraction II + III composition as taught by Hardie is simply a "starting material for the orally administerable composition" that "is then suspended in a certain salt solution, at a certain temperature and pH before it is sterile filtered." We do not find this argument convincing. The fact that Hardie teaches that the orally administerable Cohn Fraction II + III composition is suspended in salt, maintained at a particular temperature and pH, and sterile filtered does not

negate the fact that Hardie teaches a Cohn Fraction II + III composition that is suitable for oral administration. In addition, appellants' claim 28 does not preclude suspending the Cohn Fraction II + III composition in a suitable salt, maintaining it at a suitable temperature and pH, and sterile filtering the composition.

Therefore, the only difference between appellants' claimed invention and Hardie is that Hardie does not teach irradiating the composition.[1] In this regard, appellants assert (Brief, page 6), "[a]t best, Hardie merely suggests that Cohn Fraction II + III paste can be [rendered] hepatitis-safe by heat pasteurization in the presence of a stabilizer, which, in fact, teaches away from the present invention." We disagree. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." In re Gurley, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994). Nothing in Hardie can be said to discourage a person having ordinary skill in the art from using a different method of rendering a Cohn Fraction II + III composition hepatitis-safe. According to Hardie (page 4, lines 56-58), "Cohn Fraction II + III paste, the hepatitis safety of which is not known, may be rendered so by methods known in the art such as by heat pasteurization in the presence of a stabilizer." As we understand it, Hardie does not suggest that "heat pasteurization in the presence of a stabilizer" is the only way to render a Cohn Fraction II + III composition hepatitis safe. To the

[1] See Answer, page 4, wherein the examiner finds "Hardie does not teach that the composition is irradiated."

contrary, Hardie is simply providing an example of one method that is known in the art that can be used to render such a composition hepatitis safe.

As the examiner points out, a person of ordinary skill in the art at the time the invention was made would have recognized other methods of rendering an antibody composition, such as a Cohn Fraction II + III composition, hepatitis safe. In this regard, the examiner directs attention to Kent, asserting that "Kent discloses that blood products, including . . . antibodies can be sterilized via irradiation." Answer, page 4. For their part, appellants argue (Brief, page 7), "Kent does not teach, or even suggest, that the IgG composition disclosed by Hardie, let alone Cohn Fraction II+III itself, can be irradiated and orally administered." We disagree. As discussed above, a Cohn Fraction II + III composition is an antibody composition. Kent teaches that antibody compositions can be sterilized by irradiation. In this regard, Kent specifically states that the sterilization method disclosed therein "inactivates biological contaminants such as viruses. . . ." Abstract. As the examiner points out, "hepatitis is a virus." Answer, page 6. Accordingly, it would appear that the evidence of record establishes that antibodies can be sterilized by irradiation. Thus, we agree with the examiner that a person of ordinary skill in the art at the time the invention was made would have recognized that an antibody composition, such as a Cohn Fraction II + III composition, could have been sterilized by irradition.

We are not persuaded by appellants' intimation that a person of ordinary skill in the art would not recognize that such an irradiated Cohn Fraction II + III

composition could be administered orally. Brief, page 8. As the examiner points out, Kent discloses that the sterilization method can be used to sterilize food, which is typically consumed orally. Answer, page 7. In addition, we recognize appellants' assertion (Brief, page 8, emphasis removed), "one may not extrapolate sterilized IgG to irradiated Cohn II+III suitable for oral administration." It may be that appellants are of the opinion that subjecting a Cohn Fraction II + III composition to irradiation will damage the composition or render it unsuitable for oral administration. There is, however, no evidence on this record to support such an assertion. Instead, the evidence of record supports a contrary conclusion. In this regard, we find that Kent discloses,

> there is a need to provide a method of sterilizing products that is effective in removing biological contaminants while at the same time having no adverse effect on the product. The present invention has shown that if the irradiation is delivered at a low dose rate, then sterilization can be achieved without harming the product.

Kent, column 2, lines 24-29, emphasis added. For the reasons set forth above, we are not persuaded by appellants' assertion that the combination of Hurley and Kent will not result in an irradiated Cohn Fraction II + III that is suitable for oral administration.

We recognize appellants' assertion (Brief, page 10) that "there had been a long-felt need for an effective composition for the treatment of immune-mediated diseases at the time the present invention was filed." In support of this assertion, appellants direct attention to page 7, lines 12-15 of their specification which states, "[i]n view of the unsuccessful and disadvantageous modalities currently

employed to treat those disorders[2], there is a continued need to develop effective methods and compositions for the treatment of immune-mediated diseases." According to appellants (Brief, bridging sentence, pages 10-11), "[b]y identifying an oral pharmaceutical composition comprising irradiated Cohn Fraction II+III, the present invention for the first time provides a successful solution to this long-standing problem." We are not persuaded by appellants' arguments concerning long-felt need.

Establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. As set forth in In re Kahn, 441 F.3d 977, 990-91, 78 USPQ2d 1329, 1338-39 (Fed. Cir. 2006), "our precedent requires that the applicant submit actual evidence of long-felt need, as opposed to argument. This is because "[a]bsent a showing of long-felt need or the failure of others, the mere passage of time without the claimed invention is not evidence of nonobviousness." Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1325, 73 USPQ2d 1225, 1230 (Fed. Cir. 2004); accord In re Wright, 569 F.2d 1124, 1127, 193 USPQ 332, 335 (CCPA [sic] 1977)." For clarity, we direct appellants' attention to the Manual of Patent Examining Procedure (MPEP) for a discussion of long-felt need. Specifically, as set forth in MPEP 716.04 (I),

> [t]he relevance of long-felt need and the failure of others to the issue of obviousness depends on several factors. First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. In re Gershon, 372 F.2d 535, 539, 152 USPQ 602, 605 (CCPA 1967) . . .; Orthopedic Equipment Co., Inc.

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[2] As we understand it, appellants' reference to "those disorders" refers to multiple sclerosis and rheumatoid arthritis. See e.g.,appellants' specification, bridging paragraph, pages 6-7.

> v. All Orthopedic Appliances, Inc., 707 F.2d 1376, 217 USPQ 1281 (Fed. Cir. 1983). . . .
> Second, the long-felt need must not have been satisfied by another before the invention by applicant. Newell Companies v. Kenney Mfg. Co., 864 F.2d 757, 768, 9 USPQ2d 1417, 1426 (Fed. Cir. 1988). . . .
> Third, the invention must in fact satisfy the long-felt need. In re Cavanagh, 436 F.2d 491, 168 USPQ 466 (CCPA 1971).

On this record, appellants' fail to provide objective evidence demonstrating that the alleged "long-felt need" was persistent and recognized by those of ordinary skill in the art. Appellants' fail to demonstrate that the alleged "long-felt need" was not satisfied by another before the date of appellants' invention[3], or that appellants' invention in fact satisfied the alleged long-felt need in the art. Instead of providing objective evidence supporting their assertions, appellants satisfy themselves with the arguments of counsel. We note, however, that arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Accordingly, we are not persuaded by appellants' arguments concerning "long-felt need."

On reflection, we find no error in the examiner's prima facie case of obviousness. Accordingly, we affirm the rejection of claim 28 under 35 U.S.C. § 103 as being unpatentable over the combination of Hardie and Kent. As discussed supra claim 8 falls together with claim 28.

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[3] In this regard, we note the examiner's reference to Weissbart. Answer, page 8. While the examiner asserts (id.) that this document is a United States Patent, the examiner fails to identify the Patent No. or make this reference of record in the case. Accordingly, we have not considered this document. In addition, we recognize the examiner's reference to a database search using the keywords "rheumatoid arthritis or ra and treat?. . .. with the near30 describer . . . ." While we are confident that a number of documents may contain these "terms" within 30 words of each other, it is unclear on this record if any of these documents are relevant to the invention before us on review. In the event of further prosecution, we encourage the examiner to identify relevant evidence that supports his position and make this evidence of record.

Obviousness-type Double Patenting:

Claims 8 and 28 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 and 9 of copending United States Application No. 09/672,911 ('911), in view of Hardie.

At the October 17, 2006 Oral Hearing, appellants' representative affirmatively stated that in response to this rejection appellants' intend to either (1) cancel claims 8 and 9 in the '911 application, or (2) file a Terminal Disclaimer. As we understand this assertion, appellants' concede to the obviousness-type double patenting rejection of record. To date appellants have not (1) canceled claims 8 and 9 in the '911 application, or (2) filed a Terminal Disclaimer. Accordingly, we summarily affirm the rejection of claims 8 and 28 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 and 9 of copending United States Application No. 09/672,911 ('911), in view of Hardie.

SUMMARY

The rejections of record are affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Donald E. Adams
Administrative Patent Judge

Lora M. Green
Administrative Patent Judge

Richard M. Lebovitz
Administrative Patent Judge

) BOARD OF PATENT APPEALS AND INTERFERENCES

DEA/lbg

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